



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,631	11/26/2001	Makoto Hazama	011530	4677

23850 7590 08/26/2003

ARMSTRONG, WESTERMAN & HATTORI, LLP
1725 K STREET, NW
SUITE 1000
WASHINGTON, DC 20006

EXAMINER

LY, CHEYNE D

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/991,631	HAZAMA, MAKOTO	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on ____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-11 is/are pending in the application.

 4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) ☐ Claim(s) ____ is/are allowed.

6) ☒ Claim(s) 1-11 is/are rejected.

7) ☒ Claim(s) 1-6, 8, 9, and 11 is/are objected to.

8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some * c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other:
--	--

DETAILED ACTION

1. Claims 1-11 are examined on the merits.

PRIORITY

2. Acknowledgment is made to applicant's claim for foreign priority based on Japanese Application. No. 2000-362648, filed November 29, 2000. It is noted, however, that the translation of the certified foreign priority document is not in the instant application. Therefore, the priority cannot be granted without certified translation of the said certified foreign priority document if the document is in a foreign language.

OBJECTIONS

3. Claims 1-6, 8, 9, and 11 are objected to because of the following informalities: The instant claims contain steps that are indicated by circled numeral roman numbers. It is suggested that Applicant amend the claims to have the steps indicated by alphabetical letters.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5, 6, 7, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Specific to claim 5, line 3, the phrase "upper four groups" causes the claim to be vague and indefinite because it is unclear what criteria are being used to consider that the groups are upper (measured height or mathematically derived value). Clarification of the metes and bounds is required.

Art Unit: 1631

7. Specific to claims 6, line 4; and 7, line 3, the phrase "central values" causes the claims to be vague and indefinite because it is unclear what is being used to consider a ratio to be central (physical location in an array of values or mathematically derived value which center in a peak).

Clarification of the metes and bounds is required.

8. Claim 11 recites the limitation "conditions" in line 2. There is insufficient antecedent basis for this limitation in the claim.

CLAIM REJECTIONS - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robertson, Jr. et al. (US Patent No. 4,833,332) taken with Schiemenz, Jr. et al. (US 5,834,972 A) in view of Anderson (US 5,098,536 A).

11. Robertson, Jr. et al. discloses a method for sequence determination using a scanning fluorescent detection system wherein the signal is detected over a narrow range of wavelengths and the peak maxima should be spaced no closer than 2 nm (column 6, lines 44-59) and larger than system noise (column 13, lines 30-34). The said method comprises detecting signal from dye labeled terminators (column 9, lines 26-29) and wherein the signal is digital (column 12, lines 58-64 and Figures 2 and 3). "Four fluorescent dyes are used" (column 7, lines 41-42). The method comprises modulating and ratioing the signals corresponding to the fluorescent energies

Art Unit: 1631

to determine the identity of each species (base) (column 13, lines 20-34). Each nucleotide base is associated with a pair of peaks wherein the program analyzed the peaks to assign the DNA base identity of A, T, C, or G, as in instant claims 1-3, 8, and 11.

12. After assigning the base identities of A, T, C, or G, the program enters the upper data acquisition (column 15, lines 56-61), as in instant claim 5.

13. A weighted average of the two signals or the stronger of the two signals are used to determine a "peak" (column 15, lines 25-27). To distinguish closely spaced group of dyes, the center wavelength is evaluated (column 13, lines 39-44), as in instant claims 6 and 7.

14. The method Robertson, Jr. et al. is directed to the analysis of the first signal, second signal and third signal being indicative of the identity of each of the species (base) (claim 1). Further, if the current pair is the last point on the peak, the proceeds to determine the identity of the next base in the DNA sequence (column 15, lines 48-51), as in instant claim 9.

15. However, the method of Robertson, Jr. et al. does not comprise the step of performing a matrix transformation on a waveform signal or the step of eliminating peaks having irregular intervals.

16. Schiemenz, Jr. et al. discloses a method for transforming a plurality of digital input signals using a transformation matrix (column 4, lines 18-43), as in step 6 of instant claim 1 and claim 10.

17. Anderson discloses digitized results in a plot with rough lines and poor peak resolution (irregular peak intervals), "it is difficult to determine whether some of the peaks actually represent the presence of separated molecular species or are in fact noise" (column 1, lines 47-

Art Unit: 1631

54), and most of the background noise and baseline drift (irregular peak intervals) have been removed by the transformation (column 5, lines 1-3), as in instant claim 1, step 2 and claim 4.

18. Schiemenz, Jr. et al. discloses a general method to signal amplification, and more particularly to an improved method and system having a configurable digital transformer in a hybrid matrix amplifier array (column 1, lines 5-9). While, Anderson discloses a method for improving signal-to-noise in electropherogram (digital signal) (Abstract et al.); and Robertson, Jr. et al. discloses a method of performing signal amplification via a PMT to generate digital signal for sequence determination (column 11, lines 1-36). An artisan of ordinary skill in the art at the time of the instant invention would have been motivated to partake the concept emphasized by Schiemenz, Jr. et al. for an improved method of analyzing digital signal via matrix transformation and by Anderson for a method for improving signal-to-noise in digital signal. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to practiced the method of Robertson, Jr. et al. with a transformation matrix for sequence determination as taught by Schiemenz, Jr. et al. and improved signal to noise (removing irregular peak intervals) as taught by Anderson.

CONCLUSION

19. NO CLAIM IS ALLOWED.

20. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157

Application/Control Number: 09/991,631

Page 6

Art Unit: 1631


OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

23. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
8/24/03


ARDIN H. MARSCHEL
PRIMARY EXAMINER